General

Guideline Title

Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 40 p. (Diagnostics guidance; no. 8).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Whole lymph node analysis using the RD-100i OSNA system is recommended as an option for detecting sentinel lymph node metastases during breast surgery in people with early invasive breast cancer who have a sentinel lymph node biopsy and in whom axillary lymph node dissection will be considered. Details of the development of a national registry are included in Section 7 in the original guideline document.

The Metasin test is not recommended for detecting sentinel lymph node metastases in people with early invasive breast cancer in routine clinical National Health Service (NHS) practice. The Metasin test shows promise and the development of robust evidence is recommended to demonstrate its utility in clinical practice.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Breast cancer (early invasive with axillary lymph node metastasis)

Guideline Category

Diagnosis

Evaluation

Management

Technology Assessment

Clinical Specialty

Internal Medicine

Medical Genetics

Obstetrics and Gynecology

Oncology

Pathology

Surgery

Intended Users

Advanced Practice Nurses

Clinical Laboratory Personnel

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical effectiveness and cost effectiveness of using the RD-100i OSNA system and the Metasin test to detect metastases in the sentinel lymph nodes of patients having breast cancer surgery

Target Population

People with early invasive breast cancer who undergo a sentinel lymph node biopsy

Interventions and Practices Considered

Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting lymph node metastases

Major Outcomes Considered

- Diagnostic test accuracy

- Test failure rate
- Discordant test results
- Time to test result
- Clinical effectiveness including patient anxiety; number of repeat operations; time to start and nature of adjuvant therapy; morbidity and mortality from biopsies, axillary dissections, first and second operations, and treatment of cancer; and adverse events from false test results
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Peninsula Technology Assessment Group (PenTAG), University of Exeter (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Methods for Reviewing Effectiveness

Identification of Studies

The following bibliographic databases were searched in this review: Medline, Medline in process and EMBASE (all via OVID), Web of Science (including conference proceedings, via Institute for Scientific Information [ISI]), the Cochrane Library (all) and Health Economic Evaluation Database (HEED, via the Cochrane Collaboration). The searches did not use any form of limit (e.g., date). See Appendix 3 in the DAR for details.

The following trials registries were also searched: National Institutes of Health (NIH) ClinicalTrials.gov, Current Controlled Trials, World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP), European Union (EU) Clinical Trials Register. Google was also searched to identify grey literature and conference publications.

Items included after full-text screening were forward citation chased using Web of Science (Thompson Reuters). Searches were de-duplicated and managed using Endnote (X5).

Relevant studies were then identified in two stages. Titles and abstracts returned by the search strategy were examined independently by two researchers and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Two researchers examined these independently for inclusion or exclusion, and disagreements were again resolved by discussion.

Inclusion and Exclusion Criteria

Population

Studies of individuals with invasive breast cancer who underwent a (sentinel) lymph node biopsy during the primary operation to excise a suspected breast cancer were included.

Interventions and Comparators

Studies of OSNA or Metasin as used at the thresholds recommended by the manufacturer or designer were included.

The reference standard was post-operative histopathology, performed on fresh sections of tissue.

Frozen section and touch imprint cytology were excluded as comparators as they were not felt to be sufficiently feasible for widespread implementation (or intervention).

Outcomes

No study was excluded on the basis of outcomes, provided it appeared relevant to those listed in the decision problem.

- Test failure rate
- Diagnostic test accuracy
- Discordant test results
- Time to test result
- Duration of anaesthesia/time in operating theatre
- Number of repeat operations (except for re-excision of positive margins)
- Time to start and nature of adjuvant therapy

The clinical outcomes for consideration include:

- Patient anxiety associated with waiting time for result and not knowing the extent of surgery prior to operation
- Adverse events from false test results including patient distress and sequelae
- Morbidity and mortality from biopsies, axillary dissections, first and second operations and treatment of cancer

Study Design

For the review of test accuracy, the protocol made provision for all study designs unless evidence on the intervention and outcome of interest was already available from designs less open to bias as judged with reference to standard hierarchies of evidence.

Systematic reviews were used as a source for finding further studies and to compare with the Assessment Group's systematic review. For the purpose of this review, a systematic review was defined as one that has:

- A focused research question
- Explicit search criteria that are available to review, either in the document or on application
- Explicit inclusion/exclusion criteria, defining the population(s), intervention(s), comparator(s), and outcome(s) of interest
- A critical appraisal of included studies, including consideration of internal and external validity of the research
- A synthesis of the included evidence, whether narrative or quantitative

Studies were excluded if they did not match the inclusion criteria, and in particular were:

- Pre-clinical and animal
- Reviews, editorials and opinion pieces
- Case reports
- Studies with <10 participants

Beyond this, no study design was excluded unless evidence on the intervention and outcome of interest is already available from study designs less open to bias as judged with reference to standard hierarchies of evidence.

See Appendix 3 in the DAR for detailed description of search strategy.

Assessment of Cost-effectiveness: Systematic Review

Systematic Review of Existing Cost-effectiveness Evidence

Search Strategy

The Assessment Group reviewed published economic evaluations of intraoperative molecular assessment for metastasis in early breast cancer to identify evidence relevant to current National Health Service (NHS) practice. In addition to electronic databases searched in the effectiveness section, the NHS Health Economic Evaluation Database (NHS HEED) and EconLit were searched for cost, cost-effectiveness and cost-utility studies. Forward citations of identified studies were searched for any relevant publications published after the initial search.

Relevant studies were then identified in two stages. Titles and abstracts returned by the search strategy were examined independently by two

researchers and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Two researchers examined these independently for inclusion or exclusion, and disagreements were resolved by discussion.

Number of Source Documents

Assessment of Clinical Effectiveness

The electronic searches retrieved a total of 665 titles and abstracts. Fifty-nine additional papers were found by searching the bibliographies of included studies and by forward chasing. A total of 581 papers were excluded, based on screening title and abstract. Full text of the remaining 143 papers was requested for more in-depth screening, to give a total of 16 published and two unpublished papers included in the review. The process of study selection is shown in Figure 7 in the Diagnostics Assessment Report (DAR) (see the "Availability of Companion Documents" field). Fifty-eight abstracts were summarised but not reviewed.

Assessment of Cost Effectiveness: Systematic Review

- The initial search identified a total of 13 abstracts, 7 of which were of conference presentations, and the remaining constituted 4 individual studies. Two studies were identified as relevant to the review. See Appendix 7 and Appendix 8 in the DAR (see "the Availability of Companion Documents" field) for details on excluded studies.
- The External Assessment Group submitted an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Peninsula Technology Assessment Group (PenTAG), University of Exeter (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Methods of Reviewing Effectiveness

Data Extraction Strategy

Data were extracted by one reviewer using a standardised data extraction form in Microsoft Access 2010 and checked by a second reviewer. Disagreements were resolved by discussion, with involvement of a third reviewer if necessary. Data extraction forms for each included study can be found in Appendix 4 in the DAR.

Critical Appraisal Strategy

The methodological quality of the studies was assessed, where applicable to the design of the study, according to criteria specified by the *Cochrane Collaboration's Tool for Assessing Risk of Bias*. The QUADAS-2 was used for test accuracy studies.

Quality was assessed by one reviewer and judgements were checked by a second. Any disagreement was resolved by discussion, with involvement of a third reviewer as necessary. Results were tabulated and the relevant aspects described in the data extraction forms.

See Sections 4.1.4.1 and 4.1.4.2 in the DAR for information in internal and external validity.

Methods of Data Synthesis

Details of the extracted data and quality assessment for each individual study are presented in structured tables and as a narrative description. Any possible effects of study quality on the effectiveness data are discussed. Data on test accuracy are presented as sensitivity, specificity and concordance, where available.

Meta-analysis

Meta-analysis of diagnostic test accuracy was performed using the bivariate method implemented in Stata/SE 12.1 using the command metandi. Studies were only included in the meta-analysis if the numbers of true positives, true negatives, false negatives and false positives were all reported in the text or could be unambiguously inferred from other figures in the text. Meta-analysis using the full bivariate method was not performed where there were fewer than four included studies as the model cannot generally be estimated with fewer than four studies. Where the full bivariate model could not be estimated (either due to insufficient studies or other convergence errors) the Assessment Group reduced the complexity of the model by setting the correlation parameter to zero (effectively reducing the model to two independent univariate random effects analyses) and performing the analysis directly using the Stata command xtmelogit.

The bivariate method, when calculated using maximum likelihood estimation and without covariates, is equivalent to the hierarchical summary receiver operating characteristic (HSROC) model and this can be used to provide a summary receiver operating characteristic (SROC) curve and prediction region as well as a summary estimate and confidence region of sensitivity and specificity.

The SROC curve is designed to show how sensitivity and specificity are traded off against each other in different studies, through variation of the positivity threshold. If, and only if, there is reason to believe the positivity threshold might vary between studies, the Assessment Group provides a SROC curve and prediction region.

See Section 4 in the DAR for additional information on clinical effectiveness analysis.

Assessment of Cost-effectiveness: Systematic Review

Systematic Review of Existing Cost-effectiveness Evidence

Quality Appraisal

A quality appraisal was carried out on two studies retrieved in the economics literature search, using the Drummond checklist. A summary of the results are provided in Table 39 in the DAR.

Independent ERG Assessment

The main analysis compares OSNA and Metasin with histopathology from the perspective of the National Health Service (NHS). The evaluation is presented for the outcomes occurring up to the staging the axilla. In addition, a separate analysis evaluated the long-term outcomes of intra-operative testing options in terms of quality-adjusted life years (QALYs) and costs. The long-term analysis is intended as an illustration of the relative size of benefits of intra-operative diagnosis and the effect of uncertainty on its expected lasting impact.

Description of Model

The model is split into two separate sections (diagnostic and management) to encompass both immediate and long-term outcomes. As the technology is expected to have a larger impact on the short-term outcomes, it is this section that the Assessment Group particularly focusses on.

Diagnostic Pathway

Patients enter the model as those who have sentinel lymph node biopsy (SLNB) performed during their initial tumour removal. The model then splits into three different strategies, to encompass each of the possible combinations of diagnostic tests: intraoperative only (OSNA or Metasin, not in combination), histopathology only, or a combination of an intraoperative assay and follow up histopathology. These three strategies are shown in Figure 14 in the DAR. In the following descriptions, positive test results refer to results that indicate metastases in the sentinel lymph node. The

three modelled pathways are therefore:

- Current practice: SLNB is analysed using histopathology of the full node. If positive for metastases a second surgery is performed where axillary lymph node dissection (ALND) occurs.
- Add in strategy: half of the sentinel lymph node from SLNB is analysed during the tumour removal operation using one of the intraoperative tests (OSNA or Metasin). Those with a positive result receive ALND during that surgery. For those with a negative result, the other half of the sentinel lymph node is kept to be analysed with histopathology. Patients where metastases were not detected at the intraoperative stage, but whose histopathology is positive receive ALND as a second operation.
- Replacement strategy: the full sentinel lymph node is assessed by the intraoperative test, with no histopathology. Those with a positive result will receive ALND during their tumour removal.

At this stage the intermediate costs and patient outcomes are calculated. This analysis was developed in Excel.

See Section 5 in the DAR for additional information on the assessment of cost-effectiveness.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also

consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The cost-effectiveness analyses of the short-term outcomes examined the diagnostic accuracy of the intraoperative tests compared with postoperative, histopathology, and the disutility of waiting for histopathology results and having a second operation. For strategies that did not involve histopathology, the utility was 1 because there was no wait for test results or any second operations directly resulting from the intraoperative test. Only short-term quality-adjusted life-year (QALY) gains were included in these analyses.

Using the National Health Service (NHS) reference costs in the short-term model, whole-node OSNA analysis and half-node OSNA analysis dominated histopathology analysis because they were less costly and more effective. Whole-node OSNA analysis also dominated half-node OSNA analysis. It was estimated that 4.1% of the 76.5% of patients who received a negative test result from half-node OSNA analysis would end up with a positive result while waiting for confirmation by histopathology analysis, compared with 20% of patients who would receive a positive result using postoperative histopathology analysis alone.

In the short-term model, whole-node and half-node Metasin analyses dominated histopathology analysis because they were less costly and more effective. Whole-node Metasin also dominated half-node Metasin analysis. It was estimated that, of the 78.5% of patients who received a negative result by half-node Metasin analysis, 1.9% would receive a positive result while waiting for confirmation by histopathology analysis, compared with 20% of patients who would receive a positive result using postoperative histopathology analysis alone.

The cost-effectiveness analyses of the long-term outcomes examined all the costs and benefits from accurate diagnosis through to improved patient management. In these analyses, the diagnostic strategies were ordered by the number of QALYs associated with them, with whole-node OSNA analysis producing the least QALYs (9.22) and postoperative histopathology producing the most QALYs (9.32). The QALY difference is equal to 0.1 (that is, equivalent to 5 weeks of full-health life) and this difference occurs because the higher accuracy of histopathology assumed in the model leads to more correct diagnoses and appropriate subsequent treatment.

Using the NHS reference costs in the long-term model, the incremental cost-effectiveness ratio (ICER) was £4324 saved per QALY lost for whole-node OSNA analysis compared with histopathology analysis and £24,863 saved per QALY lost for whole-node Metasin analysis compared with histopathology analysis. The ICERs for whole-node analysis compared with histopathology analysis suggest that the intraoperative testing strategies save money but that there is a loss of approximately 0.1 QALY, compared with histopathology analysis.

Considerations

The Committee considered the unpublished non-peer reviewed evidence for the Metasin test. The Committee acknowledged the findings of the 2 draft unpublished studies, but noted that the studies had not been peer reviewed and therefore the results should be interpreted with caution. The Committee concluded that the test appeared promising but that there was too much uncertainty associated with the evidence to recommend use of the test in routine National Health Service (NHS) practice. The Committee was encouraging of further research on this test.

The Committee acknowledged that the model contained several assumptions that could potentially increase the uncertainty of the cost-effectiveness analysis. The Committee was of the view that, if the economic model used a more realistic cost for histopathology, it would indicate that the RD-100i OSNA system was less cost-effective than the base-case ICERs presented in the Diagnostics Assessment Report (DAR). However, given all of the uncertainty in the cost-effectiveness analyses (see section 6.13 in the original guideline document), the Committee concluded that the RD-100i OSNA system was still likely to be a cost-effective use of NHS resources.

See Sections 5 and 6 in the original guideline document for more information on cost-effectiveness.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review and economic evaluation of intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer prepared by an External Review Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The intention is that the intraoperative test results are available during surgery and may be used to determine if other axillary lymph nodes should be removed at the same time as the initial tumour. This could avoid the need for a second operation and allow subsequent treatments such as chemotherapy to begin earlier.

Potential Harms

Adverse events from false test results, including patient distress and sequelae

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed tools (see also the "Availability of Companion Documents" field) to help organisations put this guidance into practice.

Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. 40 p. (Diagnostics guidance; no. 8).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Aug

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Professor Ron Akehurst, Professor in Health Economics, School of Health & Related Research (ScHARR), University of Sheffield; Dr Trevor Cole, Consultant Clinical and Cancer Geneticist, Birmingham Women's Hospital; Dr Paul Collinson, Consultant Chemical Pathologist, St George's Hospital; Dr Sue Crawford, General Practitioner (GP) Principal, Chillington Health Centre; Professor Ian A Cree, Senior Clinical Advisor, NIHR Evaluation Trials and Studies Coordinating Centre, University of Southampton; Professor Erika Denton, National Clinical Director for Imaging, Department of Health, Honorary Professor of Radiology, University of East Anglia and Norfolk & Norwich University Hospital; Dr Steve Edwards ,Head of Health Technology Assessment, BMJ Evidence Centre; Mr David Evans, Lay representative; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Lisa Hall, Professor of Analytical Biotechnology, University of Cambridge; Professor Noor Kalsheker, Professor of Clinical Chemistry, University of Nottingham; Dr Gail Norbury, Consultant Clinical Scientist, Guy's and St Thomas' NHS Foundation Trust; Dr Mark Kroese *(Vice Chair*), Consultant in Public Health Medicine, PHG Foundation, Cambridge and UK Genetic Testing Network; Dr Peter Naylor, GP, Chair Wirral Health Commissioning Consortia; Professor Adrian Newland (*Chair*); Dr Richard Nicholas, Consultant Neurologist, Honorary Senior Lecturer, Heatherwood and Wexham Park Hospitals; Ms Margaret Ogden, Lay representative; Dr Diego Ossa, Director of Market Access Europe, Novartis Molecular Diagnostics; Mr Stuart Saw, Director of Finance, North East London and the City PCTs; Professor Mark Sculpher, Professor of Health Economics at the Centre for Health Economics, University of York; Dr Steve Thomas, Consultant Vascular and Cardiac Radiologist at Sheffield Teaching Hospitals Foundation Trust; Mr Paul Weinberger, CEO, DiaSolve Ltd, London; Mr Christopher Wiltsher, Lay representative

Specialist Committee Members: Ms Marie Hecht, Lay member; Professor Ian Kunkler, Consultant and Honorary Professor in Clinical Oncology, Edinburgh Cancer Centre; Professor Graham T Layer, Consultant surgeon and Director of Professional Standards, Royal Surrey County Hospital NHS Foundation Trust; Mr Simon Pain, Consultant Breast and Endocrine Surgeon, Norfolk and Norwich University Hospital; Mr Zenon Rayter, Consultant surgeon, North Bristol NHS Trust; Dr Deirdre Ryan, Consultant pathologist, Barts Health NHS Trust; Dr Abeer Shaaban, Consultant pathologist, St James's University Hospital

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Availability of Companion Documents

The following are available:

- Huxley N, Jones-Hughes T, Coelho H, Snowsill T, Cooper C, Meng Y, Cooper K, Hyde C, Mujica-Mota R. A systematic review and

economic evaluation of intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. Diagnostics assessment report. Exeter (UK): Peninsula Technology Assessment Group (PenTAG), Peninsula College of Medicine and Dentistry, University of Exeter; 2012. 168 p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

- Huxley N, Jones-Hughes T, Coelho H, Snowsill T, Cooper C, Meng Y, Cooper K, Hyde C, Mujica-Mota R. A systematic review and economic evaluation of intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. Diagnostics assessment report appendices. Exeter (UK): Peninsula Technology Assessment Group (PenTAG), Peninsula College of Medicine and Dentistry, University of Exeter; 2012. 144 p. Electronic copies: Available from the NICE Web site .
- Huxley N, Jones-Hughes T, Coelho H, Snowsill T, Cooper C, Meng Y, Cooper K, Hyde C, Mujica-Mota R. A systematic review and economic evaluation of intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. Diagnostics assessment report errata. Exeter (UK): Peninsula Technology Assessment Group (PenTAG), Peninsula College of Medicine and Dentistry, University of Exeter; 2012. 16 p. Electronic copies: Available from the NICE Web site .
- Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. Costing template. London (UK): National Institute for Health and Care Excellence; 2013 Aug. (Diagnostics guidance; no. 8). Electronic copies: Available from the NICE Web site .
- Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer. Podcast with Mr Zenon Rayter. London (UK): National Institute for Health and Care Excellence; 2013 Aug. (Diagnostics guidance; no. 8). Electronic copies: Available from the NICE Web site .
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer: information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Aug. (Diagnostics guidance; no. 8). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on December 31, 2014.

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